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### 510(k) Summary

**Applicant/Sponsor:** Arthrotek Inc.  
(A wholly owned subsidiary of Biomet Inc.)  
56 East Bell Drive  
P.O. Box 587  
Warsaw, IN 46581-0587  
FDA Registration #: 1825034

**Contact Person:** Gary Baker  
56 East Bell Drive  
P.O. Box 587  
Warsaw, IN 46581-0587  
Telephone: (574) 372-1568  
Fax: (574) 372-1683

**Proprietary Name:** Cannulated Arthrorivet™ and Cannulated RC Arthrorivet™

**Common Name:** Resorbable Pop Rivet

**Classification Name:** Fastener, Fixation, Biodegradable, Soft Tissue

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

Lactosorb® Pop Rivet – 510(k) K981798 cleared on July 13, 1998.

**Device Description:** Cannulated Arthrorivet™ and Cannulated RC Arthrorivet™ are resorbable rivets made of Lactosorb® Copolymer. They are designed with ribbed legs that extend during actuation to hold the rivets in the desired position. The heads incorporate spikes to grip the soft tissue and hold it in place during the healing process.

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P.O. Box 587  
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56 E. Bell Drive  
Warsaw, IN 46582

OFFICE  
574.267.6639

FAX  
574.268.2742

E-MAIL  
biomet@biomet.com

**Indications for Use:** These devices are indicated for soft tissue reattachment in the following shoulder procedures:

1. Instability repairs in the shoulder (Bankart Procedures)
2. SLAP lesion repair
3. Acromio-clavicular separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

**Summary of Technologies:** Cannulated Arthrorivet™ and Cannulated RC Arthrorivet™ are manufactured from the same materials and utilizing the same manufacturing practices as the predicate devices.

**Non-Clinical Testing:** Mechanical testing indicated equivalent or greater fixation strength of the Cannulated Arthrorivet™ and the Cannulated RC Arthrorivet™ compared to the predicate device.

**Clinical Testing:** No clinical testing was necessary for determination of substantial equivalence.

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*All trademarks are property of Biomet, Inc.*



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 5 2003

Mr. Gary Baker  
Regulatory Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581

Re: K033519

Trade/Device Name: Cannulated Arthronvet™ and Cannulated RC Arthronvet™  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/Multiple component Metallic Bone Fixation Appliances and  
Accessories  
Regulatory Class: Class II  
Product Code: HRS, JDR, MAI  
Dated: November 5, 2003  
Received: November 7, 2003

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

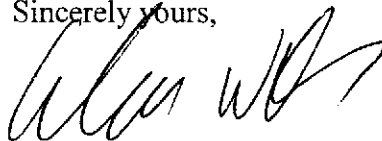
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain.

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**Statement of Indications For Use**

510(k) Number (IF KNOWN): K033519

Device Name: Cannulated Arthrorivet™ and Cannulated RC Arthrorivet™

Indications for Use: These devices are indicated for soft tissue reattachment in the following shoulder procedures:

1. Instability repairs in the shoulder (Bankart Procedures)
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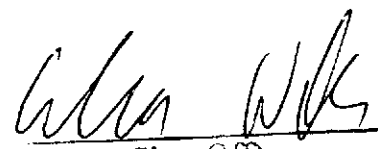
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use Ng  
(Optional Format 1-2-96)

  
Division Sign-Off  
Division of General, Restorative  
and Neurological Services

510(k) Number K033519